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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,135	02/13/2002	Akemichi Baba	010541A	5435

38834 7590 08/26/2005

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EXAMINER

QIAN, CELINE X

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 08/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/073,135

**Applicant(s)**

BABA ET AL.

**Examiner**

Celine X. Qian Ph.D.

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2005.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 14-18 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-6 and 14-18 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 13 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

Claims 1-6, 14-18 are pending in the application.

This Office Action is in response to the Amendment filed on 7/8/05.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/8/05 has been entered.

#### ***Response to Amendment***

The rejection of claims 1-6, 14-18 under 35 U.S.C. 112 1<sup>st</sup> paragraph is maintained for reasons set forth of the record mailed on 9/8/04 and further discussed below.

#### ***Response to Arguments***

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 14-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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In response to this rejection, Applicants argue that the claimed mouse is useful as a valid model of human psychiatric disorders with deficient function of PACAP gene. Applicants submitted Davids et al., Solanto et al (1998 and 2000), Gainetdinov et al (1999 ad 2000), Swerdlow et al., Lipska et al., and Kilts et al. to confirm the validity of the claimed mouse as a model of human psychiatric disorder. Applicants assert that these publication show that mice and humans are well known to react similarly with respect to their psychomotor behavior, and mice are generally considered as a valid model for psychiatric disorders. Applicants assert that consequently, a skilled artisan would recognize the claimed mouse is a valid model for human psychomotor behavior associated with dysfunction of human PACAP gene. Applicants further assert that this model can be used to identify human pathological disorders and develop treatment. Furthermore, Applicants cites Lipska's statement "animal models are important developments in investigation of the mechanisms underlying a human disease and the design of new treatments." Moreover, Applicants assert that Kilts article confirms the usefulness of a PACAP gene knockout mouse exhibiting behavioral phenotypes as a model for human behavioral phenotype caused by human PACAP gene dysfunction because it confirms the correlation mouse human with respect to behavioral dysfunction. Further, Applicants argue that the use of the present invention is not to do basic research as studying the properties of the claimed product itself or the mechanism that is involved, but to study human pathologies. Applicants assert that the model mouse is useful to identify sources and patterns of human psychiatric pathologies involving PACAP gene deficiencies which would define a "real world" use according to the guideline set forth in MPEP 2107.01. Applicants thus conclude that the claimed invention is enabled by the instant specification.

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The above arguments have been fully considered but deemed unpersuasive. The claimed mouse is not enabled by the instant specification for reasons set forth of the record mailed on 2/13/04 and 9/8/04. The references submitted by Applicants have been fully considered, however, they fail to support the enablement of the instant invention because they do not teach how to use the claimed invention as a valid model for human psychiatric disorders. Neither the specification nor the references teach what type of specific psychomotor disorder in human this mouse model represents. Without such teaching from the specification and prior art, a skilled artisan would have to engage in undue experimentation to find out what if there is a specific human psychomotor disorder is linked to deficiency of human PACAP, and whether the claimed mouse model can represent said disorder. As indicated by Davids et al., experimental models should resemble the clinical condition in pathophysiology and mimicking syndromal features, such that it can be used to predict potential new treatments (see abstract, 2<sup>nd</sup> and 3<sup>rd</sup> lines, and page 2, bridging paragraph of 1<sup>st</sup> and 2<sup>nd</sup> col). In the instant case, the specification does not teach 1) what human psychomotor disorder this mouse model represents; 2) whether the phenotype displayed by the mouse model also exists in human with such disorder. A review of the references does not provide such information as well. The examiner does not contend that animal models are useful for studying human disease, and there are various mouse models that represent specific human disorder, however, there is no evidence to establish the claimed mouse (mouse deficient in PACAP) is a valid model for a specific human disorder. While Davids et al., Solanto et al (1998 and 2000), Gainetdinov et al (1999 and 2000) discuss the animal model and ADHD, Swerdlow et al., Lipska et al., and Kilts et al. discuss the animal model and Schizophrenia, none of which mentions a human disorder linked to PACAP deficiency and

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specific symptoms of such disorder. The paragraph in Kilts et al. cited by Applicants discusses knockout mouse which exhibits behavioral phenotype relevant to specific disorder such as schizophrenia and anxiety, which has nothing to do with a knockout mouse having PACAP deficiency. As such, in view of lack of teaching from the specification and the prior art, one skilled in the art would have to engage in undue experimentation to use claimed mouse as a model for human psychiatric disorder. Therefore, this rejection is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine X Qian Ph.D.  
Examiner  
Art Unit 1636

**CELIAN QIAN**  
**PATENT EXAMINER**

